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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ODLAND, KATHRYN P	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/732,835	ROE ET AL.	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13-18 and 46-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-18 and 46-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated December 19, 2003. Claims 1-10, 13-18, and 46-65 are pending. Claims 11, 12, 19-45 and 66 have been cancelled. Applicant has presented claims 67-71 and alleged they were previously presented. Original claims filed December 7, 200 contained claims 1-45. A preliminary amendment dated June 26, 2003 canceled claims 12 and 19-45, where in contradiction applicant, in this amendment, dated December 19, 2003, considers claims 12 and 19-45 withdrawn. Thus, they are considered cancelled. Moreover, applicant in the preliminary amendment dated June 26, 2003 adds claims 46-66. Although there is a statement on page 2, that recites, "In addition, please add the following new claims 46-71." Only claims 46-66 were provided.

Applicant's amendments to the title and specification are acknowledged. The amendments to overcome the claim objections and 35 USC 112 rejections have been acknowledged.

Response to Arguments

1. Applicant's arguments filed December 19, 2003 have been fully considered but they are not persuasive.

Applicant argues that Green fails to disclose, "housing the clip and releasably holding the clip therein." Applicant states, "Neither the pusher tube 42 or the clip support fixture house the clam shell clip 22, instead leaving the clip 22 entirely exposed to the interior of the body. Each of the independed claims, either as previously

presented or as currently amended, include a housing for housing the annular clip *within*."

First it is to note that independent claim 1, recites, "a housing slidably disposed on the exterior of the elongate member, the housing configured for housing the clip and releasably holding the clip..." There is no recitation in claim 1 requiring that housing hold the clip *within*. Further, there is no mention in any of the claims that the housing holds the clip inside.

In a reasonably broad interpretation of the phrase, "**housing for housing**" it is not required that the item to be housed is housed inside. Housing is defined as: to reside; dwell, according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Thus, given this reasonably broad interpretation, the clip of Green resided at the housing (34).

Moreover, applicant argues the claim limitation, "**housing the clip and releasably holding the clip therein.**" Given a reasonably broad interpretation of the term therein, it is not required that the clip be inside some sort of **structural** container. Therein is defined as: in that place, time, or thing according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Thus, in that space or place or time or thing does not equate to inside or confined in a structural container with definitive structural features. Thus given a reasonably broad claim interpretation, applicant has failed to define structural features to define over the prior art rejection.

Applicant further agues, that Green does not disclose an annular clip. Annular is defined as: shaped like or forming a ring according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. As shown in figure 4, the ring is clearly shaped like a ring.

With regard to applicant's argument based on the 35 USC 103(a) rejection over Green in view of Hathaway it is argued that Green and Hathaway are not properly combinable. However, they are both directed toward medical closure devices and both clearly have actuators. Moreover, the combination would not be improper for it would be obvious to one with ordinary skill in the art to employ the teachings of Hathaway to include an actuator that is configured for selectively expanding the positioning elements to one of a plurality of expanded diameters for the purpose of controlling expansion.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-9, 11, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al. in EP 0774237.

Green et al. disclose an apparatus for delivering a closure element into a passage communicating with an opening into a body lumen having:

- An elongate member (20/30) having proximal and distal ends, as recited in column 6, lines 45-60 and seen in figures 2 and 3

- An annular clip (26) carried by the elongate member for closing the opening, as recited in column 6, lines 50-55 and seen in figures 2 and 3
- A locator member (60) coupled to the elongate member, where the locator member has a distal portion extending distally beyond the distal end of the elongate member, as seen in figure 15
- One or more positioning elements (62b and 64b) on the distal portion of the locator member, where the positioning elements are selectively expandable between a substantially axial compressed configuration and a substantially transverse expanded configuration, as seen in figures 12 and 15
- Positioning elements that are splines (62b and 64b) configured for expanding substantially transversely with respect to a longitudinal axis of the elongate member, as seen in figure 15
- One or more positioning elements (62b and 64b) that are a plurality of substantially flexible splines, as recited in column 8
- One or more positioning elements (62b and 64b) that are a pair of splines disposed opposite one another about the distal portion, as seen in figure 15
- Each spline that have a first fixed end (62a and 64a) and a second movable end (at the junction of 63 and 65), the second end being axially movable towards the first to cause the first end to cause an intermediate region (at 62b and 64b) of the spline to expand transversely outward, thereby defining the substantially transverse expanded configuration, (when moving from the compressed to

relaxed state the region of 63 and 65 will move toward the 62a and 64a region in order for 62b and 64b to expand outwardly

- A locator member (60) that has a control member (68) having a distal end coupled to the second end of each spline, the control member being movable axially with respect to the elongate member to selectively expand the splines between the collapsed configuration and the expanded configuration, as seen in figure 8
- An actuator (75) coupled to the locator member (60), the actuator configured for selectively expanding the positioning element from the collapsed configuration to the expanded configuration, as recited in column 9
- An actuator (75) that is configured for selectively expanding the positioning elements to a desired angle with respect to a longitudinal axis of the locator member (wherein it can be selected from the closed position to the open position and the angle of the open position is desired)
- A housing (34) slidably (slidable with respect to the sliding of the assembly via 42) disposed on an exterior of the elongate member (30), the housing configured for releasably holding the clip, where the housing is actuatable for advancing the clip distally toward the distal end of the elongate member for deploying the clip, as recited in column 7
- A elongate member (20/30) that has an introducer sheath (100) including a lumen therethrough, and wherein the locator member is removably insertable into the lumen, the distal portion of the locator member having a size for insertion

through the lumen when the positioning members are in the collapsed configuration, as recited in column 9

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 10, 13-15, 17-18, and 46-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. in EP 774237 in view of Hathaway et al. in US Patent No 5,304,184.

Green et al. also disclose an apparatus for delivering a closure element into a passage communicating with an opening into a body lumen having:

- An elongate member (20/30) having proximal and distal ends
- A locator member (60) having a distal portion extending distally beyond the distal end of the elongate member
- One or more positioning elements (62b, 64b) on the distal portion of the locator member that are selectively expandable between a substantially axially collapsed configuration and a substantially transverse expanded configuration
- Positioning elements (62b, 64b) that each have a spline with a first fixed end and a second movable end where the second end is axially movable towards the first end to cause an intermediate region of the spline to expand transversely outward, thereby defining the substantially transverse configuration

- An actuator (75) coupled to the locator member (60) configured for selectively expanding the positioning elements from the collapsed configuration to the expanded configuration
- An elongate member (20/30) that has an introducer sheath (100) and where the locator member is insertable into a lumen of the sheath, as recited in column 9
- An apparatus for delivering a closure element into a passage communicating with an opening in a body lumen having:
- A locator that is insertable into a tubular member where the locator member and the tubular member have cooperating detents for substantially securing the locator member with respect to the tubular member
- An actuator that is further configured for automatically collapsing the positioning elements to the collapsed configuration upon advancement of the housing
- A locator member that has a substantially rigid sleeve extending beyond the distal end of the sheath, the positioning elements deployable axially from within the sleeve

However, Green et al. do not explicitly recite:

- An actuator that is configured for *selectively expanding the positioning elements to one of a plurality of expanded diameters*
- Opposing positioning elements that may be expanded to *complementary angles* with respect to the longitudinal axis
- *An actuator coupled to the housing* configured for advancing the housing distally to deploy the clip therefrom

- A spring mechanism for biasing the housing distally upon activation of the actuator
- A sheath and locator member that include *cooperating detents* for substantially securing the locator member axially with respect to the sheath when the locator is fully inserted into the sheath
- An elongate member and locator member that include *cooperating detents* for substantially securing the locator member axially with respect to the elongate member
- An actuator that is configured for automatically collapsing the positioning elements to the collapsed configuration *upon advancement of the housing*

On the other hand, Hathaway teach an actuator that is configured for *selectively expanding the positioning elements to one of a plurality of expanded diameters,* see figure 18 and a spring mechanism, as recited in column 10. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Green et al. to include actuator that is configured for selectively expanding the positioning elements to one of a plurality of expanded diameters, for the purpose of controlling the expansion. Although, not explicitly recited, it would also be obvious to one with ordinary skill to have opposing positioning elements that may be expanded to complementary angles with respect to the longitudinal axis for the purpose of proper function at vessel entrances at different angles. Further, it would be obvious to include spring mechanism for biasing the housing distally upon activation of the actuator where the actuator is coupled to the housing configured for advancing the housing distally to deploy the clip therefrom. To

have the housing stationary and a push rod deploy the clip or an actuator that is coupled to the housing configured for advancing the housing distally to deploy the clip therefrom can be considered both within the scope of the invention and obvious variants to one with ordinary skill in the art. Moreover, cooperating detents would also be obvious to one with ordinary skill in the art and within the scope of the invention for providing proper alignment

Moreover, the modifications to Green et al. would provide the method for delivering a closure element into a passage communicating with an opening in a wall of a body lumen via:

- Positioning an elongate member (20, 30) through a patient's skin towards the body lumen via the passage, the elongate member includes a lumen extending between its proximal and distal ends
- Providing a locator (60) having a distal portion extending beyond the distal end of the elongate member and into the body lumen
- Expanding one or more positioning elements on the distal portion of the locator form a collapsed configuration to an expanded configuration
- Withdrawing the elongate member and locator partially until the positioning elements in their expanded configuration contact the wall of the body lumen, thereby proving a tactile indication of a location of the distal end of the elongate member
- Delivering a clip via the elongate member into the passage

- Withdrawing the elongate member and locator from the body lumen opening leaving the clip to substantially close the opening
- An elongate member that has an introducer sheath and one or [more] instruments through the lumen of the sheath into the body lumen
- Performing a diagnostic or therapeutic procedure using the one or more instruments at a location accessed via the body lumen
- A body lumen that is a blood vessel and where the procedure is at least one of angioplasty, atherectomy, stent delivery, delivery of a therapeutic agent, and tissue ablation
- An elongate member that is a tubular body where the locator is inserted into the tubular body and is axially fixed with respect to the tubular body when the locator is fully inserted into the tubular body
- Advancing a housing distally along an exterior of the elongate member where the housing is releasable holding the clip when delivering the clip

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO

Henry Bennett
Supervisory Patent Examiner
Group 3700